



This is an official
CDC Health Advisory

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Nationwide Voluntary Recall of All Products for Sterile Use from Compounding Pharmacy located in Cedar Park, Texas

Summary

The U.S. Food and Drug Administration (FDA) is alerting health care providers and patients of a voluntary nationwide recall of all products produced and distributed for sterile use by Specialty Compounding, LLC, Cedar Park, Texas. There have been recent reports of bacterial bloodstream infections potentially related to the company's calcium gluconate infusions.

CDC and the FDA are working with Texas state officials to determine the scope of the contamination.

According to the FDA, information provided by the firm stated that the recalled products (i.e., all products produced and distributed for sterile use by Specialty Compounding) were distributed directly to patients nationwide, with the exception of North Carolina, which received no products. The full text of the recall is available on the FDA website at <http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery>. Also according to the FDA, information provided by the firm stated that recalled products were also distributed to hospitals and physician offices in Texas.

Background

The Texas Department of State Health Services has reported bacterial bloodstream infections in 15 patients from two Texas hospitals who received an infusion of calcium gluconate 2 grams in Sodium Chloride 0.9 percent for Injection, supplied by Specialty Compounding. According to Texas state officials, most infections were caused by *Rhodococcus equi* and are thought to be related to the infusions. Two of the 15 patients have died. CDC does not have information that the deaths are related to recalled product. Also according to Texas state officials, cultures from an intact sample of calcium gluconate compounded by Specialty Compounding show growth of bacteria that are consistent with *Rhodococcus* species. Isolates are being evaluated by CDC to confirm the identification.

Recommendations

All sterile use products produced and distributed by Specialty Compounding are being recalled, and none of these products should be used by patients or administered to patients. Facilities, health care providers, and patients who have received the products, should immediately discontinue use, quarantine the products, and return the products to Specialty Compounding (See <http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery>).

If patients who received recalled product are experiencing symptoms, especially fever, they should consult a physician.

Patients and physicians should report adverse reactions experienced with the use of any Specialty Compounding products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. Information on reporting adverse reactions can be found at:

- <https://www.accessdata.fda.gov/scripts/medwatch/>
- Download form at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm> or call 1-800-332-1088 to request a reporting form, then complete and mail to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional Information

As more information becomes available, CDC will provide updates on the situation via the Health Alert Network.

DHEC contact information for reportable diseases and reporting requirements

Reporting of diseases is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2013 List of Reportable Conditions available at: <http://www.scdhec.gov/health/disease/reportables.htm>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2013

Mail or call reports to the Epidemiology Office in each Public Health Region.

LOW COUNTRY PUBLIC HEALTH REGION

Berkeley, Charleston, Dorchester
4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 953-0043
Fax: (843) 953-0051
Nights / Weekends: (843) 441-1091

Beaufort, Colleton, Hampton, Jasper
219 S. Lemacks Street
Walterboro, SC 29488
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Fax: (843) 549-6845
Nights / Weekends: (843) 441-1091

Allendale, Bamberg, Calhoun, Orangeburg
PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 268-5866
Fax: (843) 549-6845
Nights / Weekends: (843) 441-1091

MIDLANDS PUBLIC HEALTH REGION

Kershaw, Lexington, Newberry, Richland
2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: (888) 554-9915

Chester, Fairfield, Lancaster, York
PO Box 817
1833 Pageland Highway
Lancaster, SC 29720
Phone: (803) 286-9948
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Aiken, Barnwell, Edgefield, Saluda
222 Beaufort Street, NE
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
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PEE DEE PUBLIC HEALTH REGION

Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion
145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 915-8845

Clarendon, Lee, Sumter
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105 North Magnolia Street
Sumter, SC 29150
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Georgetown, Horry, Williamsburg
1931 Industrial Park Road
Conway, SC 29526-5482
Phone: (843) 915-8804
Fax: (843) 365-0085
Nights/Weekends: (843) 915-8845

UPSTATE PUBLIC HEALTH REGION

Anderson, Oconee
220 McGee Road
Anderson, SC 29625
Phone: (864) 260-5801
Fax: (864) 260-5623
Nights / Weekends: (866) 298-4442

Abbeville, Greenwood, Laurens, McCormick
1736 S. Main Street
Greenwood, SC 29646
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Fax: (864) 942-3690
Nights / Weekends: (866) 298-4442

Cherokee, Greenville, Pickens
PO Box 2507
200 University Ridge
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UPSTATE PUBLIC HEALTH REGION (continued)

Spartanburg, Union
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Nights / Weekends: (866) 298-4442

**DHEC Bureau of Disease Control
Division of Acute Disease Epidemiology**
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Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
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